



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

February 14, 1997

FOOD & DRUG ADMINISTRATION  
400 FERNANDEZ AVENUE

**WARNING LETTER**  
**SJN-97-06**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Rafael Rizek, M.D.  
Las Americas Blood Bank  
400 Domenech Ave., Suite 209  
Hato Rey, P.R. 00918

Dear Dr. Rizek:

During an inspection of your licensed blood bank in Hato Rey, P.R., on January 16 through 24, 1997, our investigator documented violations of section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Part 606 as follows:

- 1 Failure to follow your Standard Operating Procedure (SOP) for the preparation of Fresh Frozen Plasma [21 CFR 606.100(b)(6)] in that the centrifuge for preparation is not refrigerated in accord with your SOP.
- 2 Failure to maintain accurate processing records [21 CFR, 606.160(a)(2)] in that the production records for Fresh Frozen Plasma noted a centrifuge processing temperature of 5°C, when in fact the centrifuge refrigeration system was not functioning and the actual processing temperature was room temperature.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. An FD-483, List of Observations, (copy attached) was issued to and discussed with Mr. Victor Rodriguez, Blood Bank Supervisor at the close of the inspection. It is your responsibility to assure that your establishment is in compliance with all requirements of the Federal Regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include license suspension, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

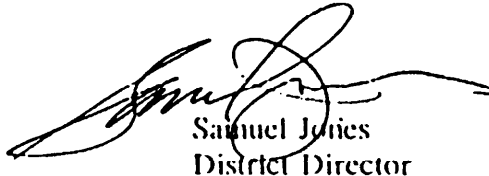
Rafael Rizek, M.D.

Your reply should be sent to the U.S. Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., Puerta de Tierra, San Juan, P.R. 00901-3223, Attention: Richard E. Dent, Compliance Officer.

If you require any assistance in understanding the content of this letter, do not hesitate to contact Mr. Dent at (787) 729-6756.

A copy of this letter has been sent to Ms. Melba Montalvo, Blood Bank Administrator.

Sincerely,



Samuel Jones  
District Director

cc: Melba Montalvo, Blood Bank Administrator